

Applicants: L. Maggi *et al.*  
Serial No.: 10/507,344  
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Docket No.: 28069-602 NATL

VS 548791  
5650169

**REMARKS/ARGUMENTS**

In this Amendment, claims 1-27 are currently amended. The amended claims are fully supported by the instant specification and prior claims. Thus, no new matter is introduced into the application by virtue of the amendments herein.

More specifically, to a large degree, the amendments to the claims are clerical in nature and are presented to conform the claim language to standard U.S. practice and to correct grammatical oversights. Support for the film coating being impermeable to aqueous fluids in currently amended claim 1 is found, for example, in the as-filed specification, *inter alia*, on page 6, lines 1-2.

Accordingly, the presently pending claims in this application are claims 1-27.

**Double patenting**

Claims 1 and 9-27 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-17 of co-pending application U.S. Serial No. 10/507,345. The Examiner states that although the co-pending claims are not identical, they are not patentably distinct from each other.

To progress the prosecution of the instant application without acquiescing as to the merits of the rejection, Applicants submit herewith a terminal disclaimer and the required fee.

Accordingly, withdrawal of the provisional rejection under the judicially created doctrine of obviousness-type double patenting is respectfully requested.

**The claims fulfill the requirements of 35 U.S.C. § 112, second paragraph**

Claims 1-27 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

The Examiner remarks that the phrase "on which have been" in claim 1 is confusing. Applicants respectfully submit that this rejection is mooted in view of currently amended claim 1. Withdrawal of the rejection is thus respectfully requested.

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**The claims fulfill the requirements of 35 U.S.C. § 102**

Claims 1, 6, 8 and 11-23 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Ayer et al. (U.S. Patent No. 4,810,502) (hereinafter "Ayer"). The Examiner opines that the product disclosed by Ayer (and depicted in Ayer's Figure 2) allegedly anticipates the therapeutic system for controlled release of one or more active ingredients with previously programmed passage.

Applicants respectfully traverse the rejection.

It is well established that to anticipate under §102, each and every limitation of a claimed invention must be disclosed in a single reference. *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (Fed. Cir. 2000; *Brown v. 3M*, 265 F.3d 1349, 60 USPQ2d 1375 (Fed. Cir. 2001).

Ayer's disclosed osmotically controlled dosage form is distinct from Applicants' presently claimed invention, which contains both structural and functional limitations that distinguish it from the dosage form and osmotic system as taught and described by Ayer.

In particular, Ayer's dosage form contains an outer coating that is semipermeable to allow the ingress of physiological media in order to start the osmotic process. Throughout Ayer's disclosure, the contemplated dosage form is described as being semipermeable. Illustratively, FIG. 2 of Ayer is described as follows: "[w]all 13 of dosage form 10 comprises a composition that is permeable to the passage of an exterior fluid present in the environment of use ... . That is, wall 13 is a semipermeable wall." *See*, Col. 4, lines 14-19 of Ayer. Also, at Col. 4, line 68 to Col. 5, lines 1-3, Ayer explains that "[a] start-up time is needed for imbibing fluid through semipermeable wall 12 for dosage form 10 to hydrodynamically dispense the components of compartment 14 ... ."

Ayer further supports the semipermeable nature of the described osmotically controlled dosage form at Col. 9, lines 12-14: "The semipermeable wall of the osmotic dosage systems can be formed in one other technique ... ." Also, at Col. 10, line 18, Ayer further describes the dosage form as follows: "Next, a semipermeable wall forming composition comprising 75 wt %

cellulose triacetate ...” Indeed, the Examiner has recognized that Ayer’s tablet is semipermeable in view of the description of Ayer as provided by the Examiner on page 4 of the 09/07/2005 Office Action.

In direct contrast to Ayer, Applicants’ presently claimed system comprises a tablet whose film coating that is insoluble in and impermeable to aqueous fluids. Thus, in view of this distinction as well as others, Applicants’ therapeutic system is inapposite to that described by Ayer.

Because Ayer fails to disclose each and every element of Applicants’ presently claimed invention, arranged as in the claim, this cited reference does not anticipate the present claims. Withdrawal of the §102(b) rejection in view of Ayer is thus respectfully requested.

Claims 1, 2, 4, 5 and 8-25 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Conte et al. (U.S. Patent No. 5,487,901) (hereinafter “Conte I”) and divisional patent to Conte et al. (U.S. Patent No. 5,650,169) (hereinafter “Conte II”). Because Conte I and II contain identical disclosures, the two citations will be discussed together.

Applicants disagree that the described pharmaceutical tablet of Conte I and II anticipates the presently claimed invention. Applicants’ presently claimed invention contains both structural and functional limitations that distinguish it from described tablet of Conte I and II.

Regarding Conte I and II, the Examiner describes the pharmaceutical tablet disclosed by Conte I and II as being “formulated with polymers as a semipermeable membrane” and “being almost completely coated with an insoluble polymeric coating ...” (09/07/2005 Office Action, page 5). These characterizations of Conte I and II demonstrate the distinct and different products described by the cited references compared with Applicants’ presently claimed therapeutic system.

Conte I and II describe tablets that are not entirely coated. In view of this feature of the tablets of Conte I and II, Conte I and II do not describe tablets that are the same as Applicants’

presently claimed invention. Applicants' presently claimed tablet is completely coated and requires a film coating that is insoluble in and impermeable to aqueous fluid.

Additionally, Applicants' tablet contains laser-generated incision(s) that delimit a detachable portion of the film coating that detaches only when the tablet contacts aqueous fluid. In contrast to Applicants' invention, Conte I and II describe a tablet in which the raised portion is removed in the finished tablet. (*See*, Col. 2, lines 42-44 and lines 54-55 of Conte I; Col. 2, lines 41-43 and lines 53-54 of Conte II; and FIGS. 1-4 of Conte I and II). The disclosure of Conte I and II clearly demonstrates that the tablet of Conte I and II is not completely or entirely coated, as is that of Applicants' presently claimed invention.

Additionally, Conte I and II disclose that the tablet coating is removed so that the core can be exposed to physiological medium to allow the core, or a layer thereof, to be available for immediate release of the ingredient in the core. (*See*, Col. 3, lines 41-40-44 of Conte I and lines 39-41 of Conte II). The contemplated tablet of Conte I and II is thus inapposite to Applicants' presently claimed invention in which there is a lag time for release of active ingredient(s), resulting from the predetermined time that it takes for the incised portion of the outer coating to be removed upon contact with aqueous fluid.

Because Conte I and II fail to disclose each and every element of Applicants' presently claimed invention, arranged as in the claim, these cited references do not anticipate the present claims. Withdrawal of the §102(b) rejection in view of Conte I and II is thus respectfully requested.

Claims 1, 3 and 6-27 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Faour (U.S. Patent No. 6,599,284) (hereinafter "Faour"). The Examiner states that Faour discloses "a controlled release osmotic device comprised of an outer layer or external coating containing active ingredient (2), an intermediate layer forming a semipermeable membrane (3), and an inner layer or core containing active ingredient (4) (Figure 4)."

Applicants respectfully disagree that Faour anticipates the presently claimed invention.

Like Ayer, Faour relates to an osmotic device and system which has a semipermeable coating surrounding a core containing active ingredient(s). *See, e.g.*, Col. 4, lines 44-45; Col. 5, lines 3-5; Col. 5, lines 19-21; Col. 6, lines 57-59 and lines 66-67 to Col. 7, lines 1-2 and Col. 8, lines 22-23 of Faour. Faour's osmotic device increases in size during use to deliver active agent. (*See*, Faour at Col. 1, lines 15-16; Col. 4, lines 6-11 and lines 24-28).

In contrast to the osmotic device described by Faour, Applicants' presently claimed invention is directed to a tablet that is impermeable to aqueous fluid and that has a film coating that is insoluble in aqueous fluids. Also in contrast to Faour, Applicants' presently claimed invention does not permit physiological medium to enter the described therapeutic system as described by Faour in order to initiate an osmotic process. Thus, Applicant's invention as presently claimed is distinct and different from the device taught and disclosed by Faour.

Because Faour fails to disclose each and every element of Applicants' presently claimed invention, arranged as in the claim, this cited reference does not anticipate the present claims. Withdrawal of the §102(e) rejection in view of Faour is thus respectfully requested.

The Examiner has indicated that U.S. Patent No. 4,160,020 to Ayer et al. and U.S. Patent No. 6,004,582 to Faour, of record, are considered pertinent to Applicants' disclosure. Applicants submit that these references differ from the presently claimed invention for reasons similar to those set forth hereinabove and acknowledge the Examiner's implicit recognition of the distinction of the claimed invention from the disclosures of these references that have been cited, but not relied on.

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### CONCLUSION

Applicants respectfully submit that the application is now in condition for allowance. An action progressing this application to issue is courteously urged.

Should any additional fees be deemed to be properly assessable in this application for the timely consideration of this Amendment, or during the pendency of this application, the Commissioner is hereby authorized to charge any such additional fee(s), or to credit any overpayment, to Deposit Account No. 50-0311 (Reference No. 28069-602 NATL).

Should a further Extension of Time be required in connection with the filing of this Amendment, the Commissioner is hereby requested to grant any such Extension of Time as may be deemed necessary, and is authorized to charge any such Extension of Time Fee as may be required to keep the application in good standing, to Deposit Account No. 50-0311 (Reference No. 28069-602 NATL).

If the Examiner believes that further discussion of the application would be helpful, she is respectfully requested to telephone Applicants' undersigned representative at (212) 692-6742 and is assured of full cooperation in an effort to advance the prosecution of the instant application and claims to allowance.

Respectfully submitted,

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